

Randomized Controlled Double-Blind-Study of Role of Recombinant Erythropoietin in the Prevention of Chronic Lung-Disease

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/12/2008	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof MI Levene

Contact details
Centre for Reproduction, Growth and Development
University of Leeds School of Medicine
The General Infirmary at Leeds
Leeds
United Kingdom
LS2 9NS

Additional identifiers

Study information

Scientific Title

Study objectives

To evaluate the role of recombinant human erythropoietin (R-HuEpo) in reducing iron infusion, which may exacerbate free radical damage, leading to chronic lung disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomized controlled double blind study

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Neonatal diseases

Interventions

Infants were randomly allocated and received either R-HuEpo (480 U/kg/wk) or placebo (4% human serum albumin) by twice weekly subcutaneous injection.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Number of days on respiratory support

Key secondary outcome(s)

Number of blood transfusions required

Completion date

06/12/1995

Eligibility**Key inclusion criteria**

1. Gestational age <32 weeks and/or birthweight <1500 g
2. Requirement for mechanical ventilation and/or supplemental oxygen at birth
3. No severe renal, hepatic or coagulation disorders or major congenital malformation
4. Still require mechanical ventilation/oxygen on day 7-14 after birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/1993

Date of final enrolment

06/12/1995

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Centre for Reproduction, Growth and Development

Leeds

United Kingdom

LS2 9NS

Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/1997		Yes	No